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April 19, 1999
William K. Hubbard
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Federal Register Request for Information:
Performance Standard for *Vibrio vulnificus*
Docket Number 98P-0504 -- Volume 64, Number 13, Page 3300-3301

Dear Mr. Hubbard,

I am writing with regard to the proposed standards proposed by the Center for Science in the Public Interest requiring pasteurization of oysters grown in waters where *Vibrio vulnificus* is found.

As a citizen, a PhD biologist and an oyster lover, I am very concerned about the implications of this petition. First of all, I believe that public policy decisions should not be made in response to the agendas of individual public interest groups, but instead should be based on sound science. Without sound scientific evidence, such a stringent standard is not warranted. Indeed, there is no guarantee that enforcing such a standard would serve the public health at all. Our society is gripped by a "zero-tolerance" attitude in terms of many types of regulations, and this is driven by interest groups, not science. I would find it very disturbing if the FDA were to make policy in response to interest groups and without the necessary scientific basis.

Required pasteurization of oysters would be a financial windfall for Ameripure Corporation, and I wouldn't be surprised if they were found to be the driving force behind this push to get such legislation. But it would mean death for the shellfish industry, as pasteurization kills the shellfish, and thus changes its freshness and texture in a way that would destroy the sensory experience of eating it.

Here are my specific comments on some of your questions:

1. Is the AmeriPure Co. technology readily employable by the shellfish industry; if not, what barriers exist, and what steps could be taken to reduce or eliminate those barriers?

The barrier is a huge one—the pasteurization process destroys the desirability of the shellfish.

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2. Other than the AmeriPure Co. process, what technologies, both present and anticipated, could significantly reduce the number of V. vulnificus in oysters while retaining the sensory qualities of a raw oyster? What is known about the ability of such technologies to reduce the number of V. vulnificus to nondetectable levels?

No. Even the Ameripure technology doesn't do that.

4. Would a performance standard have to be as low as ``nondetectable?'' Do data exist that would permit the setting of a performance standard above ``nondetectable?'' If so, at what level? Should the fact that V. vulnificus is found at low levels (less than 100 Most Probable Number/gram) in oysters in months (January and February) in which there have been no reported illnesses be taken into account when establishing a performance standard or level?

I am very suspicious of ever using "non-detectable" as a standard. This smells of this regulatory approach that says any amount of a harmful substance is bound to be harmful, and any biologist knows that is not true, especially of infectious agents. There must be sound scientific basis for establishing a standard, and if that basis is lacking that is no excuse to fall back on a standard that will economically destroy the shellfish industry and eliminate raw shellfish as a food to be enjoyed by Americans.

7. What would be the quantifiable and nonquantifiable benefits of a performance standard? Who would enjoy the benefits?

It seems to me that Ameripure would be the only beneficiary of a standard that lacks scientific basis. The oyster growers and consumers would be the big losers.

There is an entity, the Interstate Shellfish Sanitation Conference which seems to me to be the proper forum for working out these issues. The FDA should turn to this group for its expertise and consultation. The ISSC has already been successful in establishing standards for *V. parahaemolyticus* that has curbed illness on the West Coast from this bacterium. The ISSC also provides a forum for data collection and further research so that a sound scientific basis can be developed for formulating policy.The scientific basis does not exist at present for setting standards for *V. vulnificus*. I urge the FDA to refer this matter over to the ISSC for continued deliberation and at the same time provide the funding and research necessary to establish well-founded public health policy.

Sincerely,

Marcia Barinaga, PhD